RVD2008-35

Re-evaluation Decision

Metsulfuron Methyl

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

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Overview

Re-evaluation Decision

After a re-evaluation of the herbicide metsulfuron methyl, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing metsulfuron methyl for the sale and use in Canada.

An evaluation of available scientific information found that products containing metsulfuron methyl have value in the food and crop industry and do not present unacceptable risks to human health or the environment when used according to revised label directions. As a condition of the continued registration of metsulfuron methyl uses, new risk-reduction measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of metsulfuron methyl was first presented in Proposed Re-evaluation Decision PRVD2008-08, *Metsulfuron Methyl*.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of metsulfuron methyl as well as summarizes the Agency's decision and the reasons for it.

Appendix I summarizes the comments received during the consultation process and provides the PMRA's response to these comments. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-06, *Metsulfuron Methyl*. To comply with this decision, registrants of products containing metsulfuron methyl will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision, PRVD2008-06, *Metsulfuron Methyl*.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products* Act is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration. The Act also requires that products have value[4] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies rigorous, modern hazard and risk assessment methods and policies. These methods consider the unique characteristics of sensitive segments of the population in both humans (e.g. children) and organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides.

For more information on how the PMRA regulates pesticides, the assessment process and risk reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What Is Metsulfuron Methyl?

Metsulfuron methyl is a selective systemic residual sulfonylurea herbicide. It is registered for postemergent use on terrestrial food and feed crops and non-crop areas in the Prairie provinces and British Columbia. Metsulfuron methyl may be used to control a broad spectrum of annual and perennial broadleaf weeds as well as some undesirable brush or woody plants. Appendix II lists registered uses of metsulfuron metyl. Metsulfuron methyl is applied once per year at a rate of 4.5 to 90.0 g a.i./ha by ground equipment only. Metsulfuron methyl residue in soil can persist for a long period, potentially limiting recropping options. For use on wheat, barley and established creeping red fescue, metsulfuron methyl is restricted to use on soil of pH 7.9 or lower.

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3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the Pest Control Products Act: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

Health Considerations

Can Approved Uses of Metsulfuron Methyl Affect Human Health?

Metsulfuron methyl is unlikely to affect your health when used according to the revised label directions.

People could be exposed to metsulfuron methyl by consuming food and water, handling treated crops, by working as a mixer/loader/handler or by entering treated sites. The PMRA considers two key factors when assessing health risks: the dose levels where no health effects occur and the dose levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Toxicology studies in laboratory animals describe the potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using metsulfuron methyl products according to label directions.

An acute overexposure to metsulfuron methyl can produce a variety of symptoms in animals and humans. Symptoms may include weight loss, nasal secretions and stained perineal areas. Contact with the eye may cause corneal opacity, moderate inflammation of the iris and moderate to severe conjunctivitis.

Additional toxic effects include diarrhea, reduced serum protein and increased relative organ weights. Effects noted at high doses in pregnant females include increased mortality, red or orange coloured urine, decreased motor activity and impaired righting reflex. However, these effects would not occur when metsulfuron methyl products are used according to label directions. Based on the weight of evidence, metsulfuron methyl is considered non-carcinogenic. A cancer risk assessment was not required.

Although there are no risks of concern based on current uses of metsulfuron methyl, protective measures (protective personal equipment and improved work practices) are required to be included on product labels to update the label according to current standards.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Human exposure to metsulfuron methyl was estimated from residues in treated crops and drinking water, including the most highly exposed subpopulation (e.g. children one to six years old). This aggregate exposure (i.e. to metsulfuron methyl from food and drinking water) represents less than 5% of the chronic reference dose.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

MRLs for metsulfuron methyl are currently specified for kidney, fat, meat and meat byproducts of cattle, goats and hogs as well as for milk. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. The proposed amendments to the default MRL for metsulfuron methyl can be found in PRVD2008-08, *Metsulfuron Methyl*, Section 8.1.2.

Risks in Residential and Other Non-Occupational Environments

Residential and other non-occupational risks are not of concern.

Metsulfuron methyl is not registered for use in residential areas; therefore, there are no potential residential or other non-occupational risks.

Occupational Risks From Handling Metsulfuron Methyl

Occupational risks are not of concern when used according to the revised label directions.

Based on the precautions and directions for use on the original product labels reviewed for this re-evaluation and considering the use of appropriate protective equipment, the risk estimates associated with mixing, loading and applying activities meet current standards for all the scenarios and are not of concern. The required personal protection equipments are long pants, long-sleeved shirt and chemical-resistant gloves.

Occupational postapplication risks are not of concern when used according to the revised label directions.

Occupational postapplication risk assessments consider exposures to workers entering treated sites, agricultural and industrial areas. Based on the precautions and directions for use on the original product labels reviewed for this re-evaluation and the required protective measures (revised restricted-entry interval), postapplication risk estimates to restricted-entry workers performing high exposure activities (scouting) meet current standards and are not of concern.

Environmental Considerations

What Happens When Metsulfuron Methyl Is Introduced Into the Environment?

Metsulfuron methyl poses a potential risk to terrestrial and aquatic plants; therefore, additional risk-reduction measures need to be observed.

When metsulfuron methyl is applied to control weeds in crops, some of it finds its way into soil and water. However, the chemical is not expected to persist as it is rapidly broken down by soil microbes and by chemical reaction in water. The breakdown chemical products that are formed persist for a longer period of time. Both metsulfuron methyl and its breakdown products are mobile and hence can move freely in soil. However, field studies have not shown any evidence that these residues in the soil will contaminate groundwater. Water runoff on the soil surface can move the residues into nearby bodies of water such as ponds and rivers. Water monitoring of these bodies of water have revealed residues, but at concentrations below levels of concern.

When metsulfuron methyl is used for weed control in crops, there is a potential that sensitive plant species on land and in water may be exposed to the chemical as a result of the spray drifting or runoff. Some of these species are sensitive to the chemical and would be adversely affected. To minimize the potential exposure, strips of land (buffer zones) between the agricultural field and the nontarget

terrestrial or aquatic areas will be left unsprayed. The width of these buffer zones will be specified on the product label. Metsulfuron methyl is not a concern to wild birds and mammals, bees and other arthropods or aquatic organisms like fish, amphibians and invertebrates because concentrations in the environment are not expected to be harmful.

Value Considerations

What Is the Value of Metsulfuron Methyl?

Metsulfuron methyl controls a wide spectrum of broadleaf weeds in wheat, barley and forage grasses at a very low application rate (4.5 g a.i. /ha). It also controls some undesirable brush and woody plants in pasture, rangeland and non-crop areas at a low application rate.

Although a relatively small quantity is used, metsulfuron methyl reduces the economic losses caused by weeds, estimated at a total of $362.5 million in the early 1990s for wheat, barley and forage grasses. Metsulfuron methyl is the only alternative to the selective herbicides registered for use on established creeping red fescue for the control of broadleaf weeds. It is also the only alternative to the selective herbicides registered for use on pasture, rangeland and non-crop areas for the control of western snowberry, trembling aspen and other undesirable brush or woody plants. Compared to alternative herbicides, metsulfuron methyl controls late germinating weeds, has greater flexibility in application timing, provides better control of undesirable woody plants and is applied at a low rate which contributes to smaller chemical load in the environment. Although metsulfuron methyl plays a role in mitigating resistance development in weeds to other herbicide groups, consideration has to be given to resistance management as more weed species are reported to be resistant to herbicides that inhibit acetolactate synthase (such as metsulfuron methyl) than to herbicides having other modes of action.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. The directions also include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of metsulfuron methyl, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect mixer/loader/applicators
- A restricted-entry interval to protect workers re-entering treated sites
- Additional precautionary statements and directions for use to protect workers using wettable granular formulation
- Precautionary statements to avoid drift to areas of human habitation or areas of human activity

Environment

- Additional precautionary statements and directions for use, as well as buffer zones to protect non-target terrestrial and aquatic plants
- Additional precautionary statements to protect aquatic habitats from use on sites conducive to runoff

Appendix III lists all required label amendments.

Other Information

For metsulfuron methyl, the summary of assessments found in PRVD2008-08 serves as an evaluation report. Lists of references considered by the Agency in support of the registration decision are found in this Re-evaluation Decision (Appendix II). The relevant test data on which the decision is based are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Any person may file a notice of objection regarding this decision on metsulfuron methyl within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, www.pmra arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information.

Appendix I Comments and Responses

1.0 Comment on the Toxicology Uncertainty Factor

It was recommended that a 100× uncertainty factor be used to establish an acceptable daily intake, which is consistent with Regulatory Proposal PRD2008-01, *Trifloxystrobin*.

Response

The acceptable daily intake (ADI) selected for metsulfuron methyl in PRVD2008-08 was based on a NOAEL of 25 mg/kg bw/day from a two-year feeding study in rats since this was the most applicable study on which to base an ADI. However, an overall uncertainty factor of 300 was proposed to account for interspecies extrapolation (10-fold), intraspecies variability (10-fold) and seriousness of effect (threefold) resulting in an ADI of 0.0833 mg/kg bw/day (25 mg/kg bw/day ÷ 300). The additional threefold factor was applied to ensure an adequate margin of exposure (MOE) to a serious treatment-related effect, death of maternal animals, in the rabbit developmental study. This consideration of effects in the calculation of an ADI is consistent with historical practice at the PMRA.

The human health risk assessment for metsulfuron methyl published in PRVD2008-08 was examined to determine if applying the proposed uncertainty factor policy (PRO2008-01) would have resulted in different factors being applied. In turn, if this would have made a difference in the risk assessment or acceptability for continued registration for any product containing metsulfuron methyl. The lowest achieved MOE for currently registered products, used as directed on product labels, was greater than 9000. Most MOE values were substantially greater than 9000. MOE values of this low magnitude indicate that there are no concerns for human health. In addition, the dietary risk assessment indicated that the potential dietary intake represented only a small proportion of the ADI.

No currently registered uses of metsulfuron methyl were withdrawn as a result of the re-evaluation. Therefore, given any potential alteration of the proposed factor would have no material effect on the human health risk assessment, a detailed re-examination of the factors applied in the context of the new proposed uncertainty factor policy (PRO2008-01) will not be undertaken at this time. However, once the proposed uncertainty factor policy is finalized, this factor may be re-assessed at the time of any request for expansion of use.

2.0 Comment on the Proposed Statement Regarding Leaching

The registrant objected to the statement "Leaching: The use of this chemical may result in contamination of groundwater, particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow" proposed in PRVD2008-08.

Response:

The addition of the aforementioned leaching statement to product labels is not triggered by human health concerns due to exposure via drinking water, but is based on the potential leaching of the active ingredient that has been identified in the environmental risk assessment. In the case of metsulfuron methyl, as stated in PRVD2008-8, varying degrees of leaching have been identified in terrestrial dissipation field studies conducted in Canada and the United States. The potential for leaching is especially prominent in non-acidic soils because of increased solubility and decreased adsorption. Leaching in the terrestrial field dissipation studies ranged from very little leaching beyond 22 cm soil depth to leaching up to 35 cm; there was no evidence to suggest that leaching had stopped at 35 cm as soil from a greater depth was not sampled.

Unfortunately, no Canadian groundwater monitoring data are presently available to confirm or refute the presence of metsulfuron methyl. Two American groundwater monitoring studies indicate that applying metsulfuron methyl does not result in significant surface or groundwater contamination. The data are of limited value for the purpose of environmental risk assessment for the following reasons.

- There were factors that may have influenced the lack of groundwater contamination that was observed in the Florida study (Michael J.L. et al. 1991). Metsulfuron methyl was applied to poorly drained loamy sands with a soil pH ranging from 4 to 5.5; groundwater ranged from 3.6 to 6.4. The transformation of metsulfuron methyl in aerobic soil appears to be faster in acidic soils, an effect that is likely influenced by hydrolysis of metsulfuron methyl in acidic conditions. The authors concede that the lack of large amounts of precipitation and the hydrolysis of metsulfuron methyl in the acidic soil conditions may have played a substantial role in preventing significant and persistent groundwater contamination. Because the Florida study is representative of soil conditions with the lowest potential for metsulfuron methyl leaching into groundwater, the results of the study are considered to be of limited value.

- In the second study (Battaglin et al. 2000), a total of 47 pesticides or pesticide residues including metsulfuron methyl, were analysed in 25 groundwater samples (20 from municipal wells located in Iowa and 5 from observational wells in Illinois). Samples were collected in June, July and August with no replication and the number of sampling events during this period was not reported. In addition, no information was available regarding the use of metsulfuron methyl in the vicinity of the sampling sites such as the application rate applied, the timing of the applications and the addition to groundwater flow. Without this information, it is difficult to establish whether the non-detection of metsulfuron methyl at the groundwater sampling sites resulted from non-transport, inadequate timing of sampling or improper location of sampling points relative to the treated fields.

While the terrestrial field dissipation studies and groundwater monitoring studies do not clearly show evidence (prove) that residues in soil will contaminate groundwater, the PMRA considers all available environmental fate and transport data to provide an overall picture of how a pesticide will move in the environment, including its potential to reach groundwater.

Collectively, the following chemical characteristics indicate that the use of metsulfuron methyl may result in contamination of groundwater.

- Metsulfuron methyl is shown to be slightly persistent to persistent under aerobic soil conditions depending on the soil type
- Adsorption/desorption and soil column leaching studies show that metsulfuron methyl has the potential to be mobile in a variety of soils.
- Metsulfuron methyl meets all leaching criteria set out by Cohen et al. (1984) and the groundwater ubiquity score (Gustafson 1989) of 2.4 to 7.9 indicates this active ingredient has a high probability of leaching in soils.

Based on this evidence, the PMRA feels that the addition of the proposed leaching statement to all metsulfuron methyl product labels is appropriate. The PMRA would accept a Prospective Groundwater Study (PGW) to verify whether the use of metsulfuron methyl results in groundwater contamination. The data collected in a PGW study would need to be representative of areas of metsulfuron methyl use in Canadian regions and include soils with the greatest leaching potential (i.e. non-acidic soils and soils in a high water table).

3.0 Comment on Buffer Zone

The registrant objected to the use of the Hawthorn study (Kjaers et al. 2006) to establish an endpoint for the terrestrial buffer zone calculation. The registrant suggested that it is a non-guideline study and it lacks certain key elements to be considered acceptable.

The registrant requested the following changes to buffer zones for uses of metsulfuron methyl products (Registration Numbers 23005, 25578 and 25579) on non-crop areas.

- The label should specify the use of a minimum coarse spray quality for these uses and the buffer zone for these applications should be re-calculated based on this adjustment.
- Buffer zones for protection of terrestrial habitats should not be required for use on rights-of-way, including railroad ballast, rail and hydro rights-of-way, utility easements, roads and training grounds and firing ranges on military bases.

Response

The PMRA considers all available and relevant information when revaluating an active ingredient. This often includes studies available in the open literature that do not follow the standard guidelines of the Organisation for Economic Co-operation and Development (OECD) and the United States Environmental Protection Agency (USEPA). The PMRA will accept such studies if they are determined to be scientifically valid and of value in terms of the risk assessment.

The PMRA agrees that the 2006 Kjaer et al. study is representative of a coverage spray rather than true drift deposition. As stated in the study, the sprayer was held vertically to spray a belt covering the Hawthorn with a solution from the ground and up to 2.5 m above the ground. The dosages were 0 (control), 0.05, 0.1, 0.2 and 0.4 times the recommended field rate in Denmark (4 g a.i./ha). This method of application is similar a standard guideline Tier 2 vegetative vigor test; effects to plants during the vegetative growth period of development are assessed at multiple pesticide exposure doses which are received as a foliar or soil cover spray. A positive control is not a requirement for OECD or USEPA guidelines for terrestrial vascular plants; therefore, the PMRA does not consider the lack of a positive control in the 2006 Kjaer et al. study to be a deficiency.

The actual deposition of metsulfuron methyl was measured in each Hawthorn using a glycine tracer added to the spray solution. Page 230 of the study states that, "Immediately after spraying, three leaves, placed close to the shoots marked for sampling, were collected in each sprayed tree..." for glycine determination. Samples, therefore, were taken from areas situated close to where the actual deposition measurements were made. Metsulfuron methyl is a systemic herbicide with foliar and soil activity and it works rapidly after it is taken up by the plant (EXTOXNET 1996). Therefore, although there is no indication whether the sampling technique was random, a lack of sampling randomness likely would not have influenced the study results. The PMRA considers the level of detail for the study design described in Kjaer et al. 2006, acceptable.

Typical risk assessment endpoints effect concentration 25% (EC_{25}) and effect concentration 50% (EC_{50}) could not be derived from the data provided in the published studies. However, using supplemental raw data provided by the study authors, an EC_{25} of 0.0001 $\mu g/cm^2$ was approximated based on reduced mature berry production in the year of spraying (equivalent to 0.01 g a.i/ha). Given that this endpoint was the most sensitive among the terrestrial plant endpoints, the PMRA used this value in the screening level assessment presented in PRVD 2008-08 and subsequently the calculation of the terrestrial buffer zones.

To take into consideration the entire terrestrial plant toxicity dataset available, the PMRA determined the risk assessment toxicity endpoint from the distribution of available terrestrial plant toxicity data, rather than simply using the most sensitive EC_{25} value. The toxicity endpoints included in the species sensitivity distribution (SSD) were obtained from registrant provided toxicity studies on onions, corn, wheat, sorghum, sugar beets, soybeans, peas, tomatoes, canola and cucumbers (DuPont Report Number AMR 3242-94, PMRA# 1076047) and Hawthorn (Kjaer et al 2006, PMRA# 1324293). Given the vegetative vigour (i.e. shoot weight) in the DuPont study was more sensitive than seedling emergence to metsulfuron methyl, the seedling emergence data was not considered for the SSD.

When calculating the SSD, the PMRA uses the EC_{50} rather than the EC_{25} which is used in the screening level assessment. The 5th percentile of the species sensitive distribution (HC_5) for the EC_{50} at 50% confidence intervals was calculated using the SSD program ETx2 (version 2.0). The HC_5 calculation was 0.02 g a.i./ha. This value was used for terrestrial plants risk assessment and subsequently the terrestrial buffer zone calculation. The revised terrestrial buffer zones for metsulfuron methyl products are presented in the table below.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrub lands), and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Application Rate (and use)*	**Buffer Zones (in metres) Required for the Protection of:**		
	Freshwater Habitat of Depths:		**Terrestrial Habitat**
	0.8 m	**> 1 m**	
4.5 g a.i./ha (crops)	1	1	4
12 g a.i./ha (pasture and rangeland)	1	1	10
15 g a.i./ha (pasture and rangeland)	1	1	10
18 g a.i./ha (pasture and rangeland)	1	1	10
60 g a.i./ha (non-crop areas)	2	1	35
90 g a.i./ha (non-crop areas)	3	1	45

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%.

These buffer zones were calculated using the ASAE spray quality classification of coarse. As such, the following statement must be added to all product labels under the section entitled **DIRECTIONS FOR USE.**

> DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) coarse classification.
>
> For products containing metsulfuron methyl used on non-crop areas (Registration Numbers 23005, 25578 and 25579), the following footnote will be added to the buffer zone table under DIRECTIONS FOR USE:
>
> Buffer zones for the protection of terrestrial habitats are not required for use on rights-of-way including railroad ballast, rail and hydro rights-of-way, utility easements, roads, and training grounds and firing ranges on military bases.

4.0 Comment

There are typographical errors (the maximum application rate listed for British Columbia) in RVD2008-08, Appendix II.

Response

The errors have been corrected in the revised table in Appendix II of this Re-evaluation Decision.

Appendix II Registered Uses of Metsulfuron Methyl as of 9 August 2006[1]

Use-Site Category	Sites		Weeds[2]	Maximum Application Rate (g a.i./ha)	Use Supported?[3]
13, 14 Terrestrial Feed Crops and Terrestrial Food Crops	Wheat (spring and durum)	Prairie provinces and Peace River Region of British Columbia (Soil pH 7.9 or lower)	A	4.5	Y
	Barley				
13 Terrestrial Feed Crops	Established creeping red fescue				
	Established creeping red fescue, orchard grass, crested and intermediate wheat grass for feed or seed production		A plus narrow-leaved hawksbeard		M
	Pasture and rangeland	Prairie provinces and British Columbia	Western snowberry	15	Y
			Wild rose	18	
		British Columbia	Field scabious and perennial pepperweed	12 to 18	M
13, 16 Terrestrial Feed Crops and Industrial and Domestic Vegetation Control for Non-food Sites	Rough turf and non-crop areas	Prairie provinces and British Columbia	B	12	Y
			B plus western snowberry	15	
			C	18	
		British Columbia	Field scabious and perennial pepperweed	12 to 18	M
	Rangeland and non-crop area (utility rights of way, roadsides, industrial sites, fence lines)	Prairie provinces and British Columbia	Balsam poplar and willow	60	Y
			Cherry and trembling aspen	90	

1 The formulation type for all supported end-use products is wettable granules. Application is made once per year by ground equipment only. No aerial application is allowed for any uses. Information on application equipment and the number of applications is based on both label use information and information provided by the registrant under DACO 5.2. Uses of tank mix products including the prepackaged tank mixes are not presented.

2 A = Ball mustard, blue bur, Canada thistle*, chickweed, common groundsel, corn spurry, cow cockle, flixweed, green smartweed, hemp-nettle, kochia, lady's-thumb, lamb's-quarters*, prostrate pigweed, redroot pigweed, Russian thistle*, scentless chamomile, shepherd's-purse, sow thistle (annual; perennial)*, stinkweed, stork's-bill, tartary buckwheat, toad flax*, volunteer rapeseed**, wild buckwheat*, wild mustard

B = Common tansy, kochia, Russian thistle, scentless chamomile, sweet clover, Canada thistle*, sow thistle*, dandelion*

C = Common tansy, kochia, Russian thistle, scentless chamomile, sweet clover, Canada thistle*, sow thistle*, dandelion and western snowberry

3 Y = Use is currently registered and supported by the registrant

M = Use was added as a User Requested Minor Use Label Expansion and is supported by the registrant.

* Suppression only

** Metsulfuron methyl alone will not control imazethapyr-tolerant canola varieties.

Appendix III Revised Label Amendments for Commercial Class Products Containing Metsulfuron Methyl

Canadian commercial end-use product labels must be amended to include the following statements to further protect workers and the environment.

FOR ALL FORMULATIONS

Add to **DIRECTIONS FOR USE:**

Do not re-enter treated fields until 12 hours after application. Apply only when the potential for drift to areas of human habitation or areas of human activity (houses, cottages, schools and recreational areas) is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

Field sprayer application:

DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty.

DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) coarse classification.

For application to rights-of-way, buffer zones for protection of sensitive terrestrial habitats are not required; however, the best available application strategies which minimize off-site drift, including meteorological conditions (e.g. wind direction, low wind speed) and spray equipment (e.g. coarse droplet sizes, minimizing the height above canopy), should be used. Applicators must, however, observe the specified buffer zones for protection of sensitive aquatic habitats.

Buffer zones:
The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrub lands) and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Application Rate (and use)*	Buffer Zones (in metres) Required for the Protection of:		
	Freshwater Habitat of Depths:		Terrestrial Habitat
	0.8 m	> 1 m	
4.5 g a.i./ha (crops)	1	1	4
12 g a.i./ha (pasture and rangeland)	1	1	10
15 g a.i./ha (pasture and rangeland)	1	1	10
18 g a.i./ha (pasture and rangeland)	1	1	10
60 g a.i./ha (non-crop areas)	2	1	35
90 g a.i./ha (non-crop areas)	3	1	45

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

The following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayers, inter-row hooded sprayers, spot treatment, soil drench and soil incorporation.

Add to **PRECAUTIONS**:

Mixers, loaders and applicators must wear long-sleeved shirts, long pants and chemical-resistant gloves (gloves are not required for groundboom sprayers).

Add to **ENVIRONMENTAL HAZARDS**:

TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

Runoff:
To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g. soils that are compacted or fine textured such as clay).

Avoid application of this product when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Leaching:
The use of this chemical may result in contamination of groundwater, particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow.

Add to **DISPOSAL:**

Disposal statements must be in compliance with PMRA Regulatory Directive DIR99-04, *Disposal Statements for Control Product Labels*.

FOR WETTABLE GRANULE FORMULATIONS

Add to **DIRECTIONS FOR USE:**

Drop intact water-soluble package (WSP) directly into spray tank. The WSP and pesticide will dissolve readily in water.

Do not allow the WSP to become wet prior to use. Do not handle individual WSP with wet hands or wet gloves as this may cause breakage. Do not remove WSP from over-wrap container except for immediate use.

Do not open water-soluble bags or attempt to remove the contents from them. The contents are not designed to be re-measured or subdivided.

Do not use opened or punctured WSP.

If broken WSP is found when the over-wrap bag is opened, avoid contact with, and inhalation of the product. Handle with chemical-resistant gloves and dispose of broken WSP according to the DISPOSAL section.

FOR FORMULATION PCP Reg. No. 25578 and 25579:
On the primary panel, the statement that reads " . . . ALSO, FOR CONTROL OF UNDESIRABLE BRUSH/WOODY PLANT SPECIES IN PASTURE, RANGELAND, AND NON-CROP AREAS IN THE PRAIRIE PROVINCES." must be revised to read " . . . ALSO, FOR CONTROL OF UNDESIRABLE BRUSH/WOODY PLANT SPECIES IN RANGELAND AND NON-CROP AREAS IN THE PRAIRIE PROVINCES." to delete the unspecified use on pasture.

FOR FORMULATION PCP Reg. No. 23005, 25578 and 25579:

Under the heading **DIRECTIONS FOR USE**, the subheading "ROUGH TURF AND NON-CROP AREAS" must be changed to read "ROUGH TURF AND NON-CROP AREAS such as

Utility Rights of Way, roadsides, industrial sites, fence lines" to achieve a consistent description of non-crop areas.

Under the heading **DIRECTIONS FOR USE**, below the buffer zone table, the following footnote must be added.

> ** Buffer zones for the protection of terrestrial habitats are not required for use on rights-of-way including railroad ballast, rail and hydro rights-of-way, utility easements, roads, and training grounds and firing ranges on military bases.

References

Studies considered in the Chemistry Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA Document Number	Reference
1166592	2004, Metsulfuron methyl 20 SG End-Use Product Soluble Granule Herbicide Formulation: Laboratory Study of Storage Stability and Corrosion Characteristics, 008-152, MRID: N/A, DACO: 3.5.10,3.5.14

B. ADDITIONAL INFORMATION CONSIDERED

Published Information

British Crop Protection Council, The e-Pesticide Manual (Thirteenth Edition) Version 3.1: 555 Metsulfuron Methyl, DACO: 2.14.9

Studies considered in the Health Risk Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA Document Number	Reference
1242523	DPX T6376 WEED KILLER (TECH ACTIVE) - ACUTE ORAL TOX - RATS, DACO: 4.2.1
1242524	DPX T6376 WEED KILLER (TECH ACTIVE) - ACUTE ORAL TOX - RATS, DACO: 4.2.1
1242525	DPX T6376 WEED KILLER (TECH ACTIVE) - ACUTE ORAL TOX - RATS, DACO: 4.2.1
1247968	ORAL TOXICITY APPROPRIATE LETHAL DOSE IN DOGS, DACO: 4.2.1
1242527	DPX T6376 WEED KILLER (TECH ACTIVE) - ACUTE SKIN ABSORPTION LD50 - RABBITS, DACO: 4.2.2
1242528	DPX T6376 WEED KILLER (TECH ACTIVE) INHALATION LC50 - RATS, DACO: 4.2.2
1242529	DPX T6376 WEED KILLER (TECH ACTIVE) INHALATION LC50 - RATS, DACO: 4.2.3

PMRA Document Number	Reference
1242531	DPX T6376 WEED KILLER (TECH ACTIVE)- EYE IRRITATION TEST IN RABBITS, DACO: 4.2.4
1242532	DPX T6376 WEED KILLER (TECH ACTIVE)- EYE IRRITATION TEST IN RABBITS, DACO: 4.2.4
1242535	DPX T6376 WEED KILLER (TECH ACTIVE)- SKIN IRRITATION TEST ON RABBITS, DACO: 4.2.5
1242536	DPX T6376 WEED KILLER (TECH ACTIVE)- PRIMARY SKIN IRRITATION AND SENSITIZATION TEST ON GUINEA PIGS, DACO: 4.2.5,4.2.6
1242534	DPX T6576 WEED KILLER (TECH ACTIVE) - PRIMARY SKIN IRRITATION AND SENSITIZATION TEST ON GUINEA PIGS, DACO: 4.2.5,4.2.6
1242526	DPX T6376 WEED KILLER (TECH ACTIVE) - 10-DOSE ORAL SUBACUTE - RATS, DACO: 4.3.1
1242537	90 DAY FEEDING STUDY AND ONE GENERATION REPRODUCTION STUDY WITH INT-6576 IN RATS, DACO: 4.3.1,4.5.1
1247958	SUBCHRONIC DERMAL TOXICITY STUDY (21 DAYS) IN RABBITS, DACO: 4.3.4
1247957	(CONT'D FROM ROLL 239) A COMBINED THREE-MONTH AND ONE YEAR FEEDING STUDY IN DOGS, DACO: 4.4.1
1247548	A COMBINED THREE-MONTH AND ONE-YEAR FEEDING STUDY IN DOGS (CONT'D ON ROLL 240), DACO: 4.4.1
1240843	90 DAY & LONG TERM FEEDING STUDY IN MICE, DACO: 4.4.1,4.4.2
1240844	90 DAY & LONG TERM FEEDING STUDY IN MICE, DACO: 4.4.1,4.4.2
1247960	ONCOGENICITY - SUPPLEMENT TO PATHOLOGY REPORT OF LONG TERM FEEDING STUDY IN MICE, DACO: 4.4.2
1247544	2 - GENERATION, FOUR LITTER REPRODUCTION STUDY IN RATS - FINAL REPORT, DACO: 4.5.1
1247539	CHRONIC FEEDING STUDY WITH CONCURRENT 2-GENERATN REPRODUCTN STUDY IN RATS--CHRONIC PHASE (CONTD FROM ROLL 236), DACO: 4.5.1
1247540	CHRONIC FEEDING STUDY WITH CONCURRENT 2-GENERATN REPRODUCTN STUDY IN RATS--CHRONIC PHASE (CONTD FROM ROLL 236), DACO: 4.5.1
1247541	CHRONIC FEEDING STUDY WITH CONCURRENT 2-GENERATN REPRODUCTN STUDY IN RATS--CHRONIC PHASE (CONTD FROM ROLL 237), DACO: 4.5.1

PMRA Document Number	Reference
1247542	CHRONIC FEEDING STUDY WITH CONCURRENT 2-GENERATN REPRODUCTN STUDY IN RATS--CHRONIC PHASE (CONTD FROM ROLL 237), DACO: 4.5.1
1247543	CHRONIC FEEDING STUDY WITH CONCURRENT TWO-GENERATION REPRO STUDY IN RATS - CHRONIC PHASE (CONT'D FROM ROLL 238), DACO: 4.5.1
1247952	CHRONIC FEEDING STUDY WITH CONCURRENT TWO-GENERATION REPRODUCTION STUDY IN RATS - CHRONIC PHASE (CONT'D ON ROLL 237), DACO: 4.5.1
1247953	CHRONIC FEEDING STUDY WITH CONCURRENT TWO-GENERATION REPRODUCTION STUDY IN RATS - CHRONIC PHASE (CONT'D ON ROLL 237), DACO: 4.5.1
1240118	EMBRYO-FETAL TOX & TERATOGENICITY STUDY OF INT-6376 IN RATS SEGMENT II - EVALUATION, DACO: 4.5.2
1240107	1982, TERATOGENICITY STUDY OF INT-6376 IN NEW ZEALAND WHITE RABBITS SEGMENT II - EVALUATION, 104-003, MRID: 00125836, DACO: 4.5.3
1240135	CHO/HGPRT ASSAY FOR GENE MUTATION, DACO: 4.5.4
1240134	IN VITRO ASSAY FOR CHROMOSOME ABERRATIONS IN CHINESE HAMSTER OVARY (CHO) CELLS, DACO: 4.5.4
1240133	IN VIVO BONE MARROW CYTOGENETIC STUDY IN RATS, DACO: 4.5.4
1247979	IN VIVO MOUSE MICRONUCLEUS ASSAY, DACO: 4.5.4
1240131	INT-6376-22 : UNSCHEDULED DNA SYNTHESIS/RAT HEPATOCYTES IN VITRO, DACO: 4.5.4
1240136	MUTAGENICITY EVALUATION IN SALMONELLA/TYPHIMURIUM, DACO: 4.5.4
1240848	MEDIAN LETHAL DOSE (LD50) IN RATS-EPA PROPOSED GUIDELINES, DACO: 4.6.1
1240849	ACUTE SKIN ABSORPTION LD50 TEST ON RABBITS, DACO: 4.6.2
1243054	EYE IRRITATION TEST IN RABBITS, DACO: 4.6.4
1240850	SKIN IRRITATION TEST ON RABBITS FOR EPA PESTICIDE REGISTRATION, DACO: 4.6.5
1240851	PRIMARY SKIN IRRITATION & SENSITIZATION TEST ON GUINEA PIGS, DACO: 4.6.6
1406318	2005, DACO 5.2: USE DESCRIPTION/SCENARIO FOR METSULFURON METHYL (ALLY AND ESCORT) HERBICIDE, DACO: 5.2

PMRA Document Number	Reference
1183255	USE DESCRIPTION/SCENARIO - APPLICATION PRACTICES AND DELIVERY SYSTEMS IN WESTERN CANADA AS THEY RELATE TO ESCORT HERBICIDE FOR BRUSH CONTROL [ESCORT;SUBN.#96-1844;REGN.#23005;SUBMITTED JUNE 12, 1998;VOLUME 1 OF 1], DACO: 5.2
1184227	FATE OF METSULFURON METHYL INGESTED BY DAIRY COWS, THE DATA USED BY EPA TO SET THEIR TOLERANCE. THIS STUDY ADDRESSES DISCREPANCY IN THE CATTLE FEEDING STUDY, L.W. HERSHBERGER AND D.W. MOORE II, REVISED JULY 25, 1985 (AMR-167-83;REVISION#1) [ESCORT HERBIC
1240086	DPX-T6376 WEED KILLER (TECH) - METABOLISM IN GREENHOUSE GROWN WHEAT, DACO: 6.3
1247990	METABOLISM OF 14C-METSULFURON METHYL IN FIELD-GROWN BARLEY, DACO: 6.3
1248001	METABOLISM OF 14C-METSULFURON METHYL IN FIELD-GROWN WHEAT, DACO: 6.3
1247546	FATE OF METSULFURON METHYL INGESTED BY DAIRY COWS, DACO: 6.4
1247545	METABOLISM OF 14C METSULFURON METHYL IN THE GOAT, DACO: 6.4
1205209	METABOLISM OF THE 14C-METSULFURON METHYL WHEAT METABOLITE A IN A GOAT, DACO: 6.4
1137011	ANALYSIS OF METSULFURON METHYL (ALLY) IN GRASS BY LIQUID CHROMATOGRAPHY (P65.REP)(MARCH 15-22 1990), DACO: 7.2.1
1156246	ANALYSIS OF METSULFURON METHYL (ALLY) IN GRASS BY LIQUID CHROMATOGRAPHY PERIOD COVERED BY STUDY MARCH 15-22,1990 (P65.REP), DACO: 7.2.1
1135908	ANALYSIS OF METSULFURON METHYL (ALLY) IN GRASS BY LIQUID CHROMATOGRAPHY PERIOD COVERED BY STUDY: MARCH 15-22 1990 (REFP65.REP), DACO: 7.2.1
1240852	DET OF RESIDUES OF METSULFURON METHYL IN CROPS BY LIQUID CHROMATOGRAPHY, DACO: 7.2.1
1240087	DETERMINATION OF RESIDUES OF DPX-T6376 BY LIQUID CHROMATOGRAPHY, DACO: 7.2.1
1205194	DETERMINATION OF RESIDUES OF METSULFURON METHYL BY LIQUID CHROMATOGRAPHY, DACO: 7.2.1

PMRA Document Number	Reference
1205200	DETERMINATION OF RESIDUES OF METSULFURON METHYL METABOLITES A & A1 IN CEREAL GRAIN CROPS BY LIQUID CHROMATOGRAPHY, DACO: 7.2.1
1137509	THE DETERMINATION OF METSULFURON METHYL RESIDUES IN CROPS BY LIQUID CHROMATOGRAPHY EQUIPPED WITH PHOTOCONDUCTIVITY DETECOR (HAS-A022.22)(ALLY), DACO: 7.2.1
1156248	THE DETERMINATION OF METSULFURON METHYL RESIDUES IN CROPS BY LIQUID CHROMATOGRAPHY EQUIPPED WITH PHOTOCONDUCTIVITY DETECTOR-ALLY (A022.002), DACO: 7.2.1
1243056	BARLEY, OATS, WHEAT GRAIN, DACO: 7.4.2
1248005	CROP ROTATION STUDY WITH 14C-METSULFURON METHYL IN THE FIELD, DACO: 7.4.2
1205213	HYDROLYSIS OF 14C-4-METHOXY-6-METHYL-1,3,5-TRIAZIN-2-AMINE, DACO: 7.4.2
1205205	METSULFURON METHYL METABOLITE A- BARLEY STRAW, DACO: 7.4.2
1205206	METSULFURON METHYL METABOLITE A- RESIDUE ANALYSIS- BARLEY GREEN FORAGE, DACO: 7.4.2
1205207	METSULFURON METHYL METABOLITE A- RESIDUE ANALYSIS- WHEAT GRAIN, GREEN FORAGE AND STRAW, DACO: 7.4.2
1205204	METSULFURON METHYL METABOLITE A- RESIDUE ANALYSIS- WHEAT GREEN FORAGE, DACO: 7.4.2
1205201	METSULFURON METHYL METABOLITE A- WHEAT GRAIN AND STRAW, DACO: 7.4.2
1205203	METSULFURON METHYL METABOLITE A- WHEAT HAY, DACO: 7.4.2
1205195	METSULFURON METHYL RESIDUE ANALYSES- BARLEY, DACO: 7.4.2
1205197	METSULFURON METHYL RESIDUE ANALYSES- OATS, DACO: 7.4.2
1205196	METSULFURON METHYL RESIDUE ANALYSES- WHEAT, DACO: 7.4.2
1205212	RESIDUE CROP ROTATION STUDY WITH 14C-ALLY HERBICIDE IN THE GREEN HOUSE, DACO: 7.4.2
1205211	Metabolism of (triazine-2-14C) metsulfuron methyl in the rat (AMR-405-85). E.I. DuPont de Nemours & Co., Inc. Haskell Laboratory for Toxicology and Industrial Medicine. May 1986.

PMRA Document Number	Reference
1247547	Metabolism of 14C-metsulfuron methyl in rats (AMR-108-83). E.I. Du Pont de Nemours & Co., Inc. Haskell Laboratory for Toxicology and Industrial Medicine. June 27, 1986.
1601367	Metsulfuron methyl: acute oral toxicity study in mice. The Institute of Environmental Toxicology, Tokyo, Japan. Study No. IET 91-0094. December 10, 1991.
1601358	Assessment of IN T6376-74 in the in vitro unscheduled DNA synthesis assay in primary rat hepatocytes. Haskell Laboratory Report No. 574-90. MR No. 4581-834/058. November 16, 1990 (suppl. September 9, 1993).

B. ADDITIONAL INFORMATION CONSIDERED

Published Information

U.S. EPA. Federal register environmental documents. Notice of filing of pesticide petitions (metsulfuron methyl). March 19, 1998 http://www.epa.gov/fedrgstr/EPA-PEST/1998/March/Day-19/p7141.htm

U.S. EPA. Federal register environmental documents. Metsulfuron methyl; pesticide tolerances for emergency exemptions. December 16, 1999 http://www.epa.gov/fedrgstr/EPA-PEST/1999/December/Day-16/p32652.htm

U.S. EPA. Federal register environmental documents. Metsulfuron methyl; pesticide tolerance. August 7, 2002 http://www.epa.gov/fedrgstr/EPA-PEST/2002/August/Day-07/p19807.htm

EU. Final. Review report for the active substance metsulfuron methyl. European Commission. Health & Consumer Protection Directorate-General.. August 14, 2000 http://ec.europa.eu/food/plant/protection/evaluation/exist_subs_rep_en.htm

PP#3F4215: Human health risk assessment for the Section 3 registration of metsulfuron methyl on grain sorghum. EPA, 2002

Dietary exposure analysis for the proposed use of metsulfuron methyl on wheat and barley. EPA series 361. EPA, 1993

Metsulfuron methyl - Report of the FQPA safety factor committee - EPA series 361

Ally Herbicide (metsulfuron methyl) : tolerance petition for grain sorghum (grain, fodder, forage and hay) with the aprropriate label modification. EPA, 1993

Evaluation on: Metsulfuron methyl, July 1991 - Pesticide Safety Directorate

Unpublished Information

PMRA Document Number	Reference
1551946	1984, DPX-T6376 herbicide, DACO: 4.8
1551947	1985, DPX-T6376 Submission (09/05/85) - Tumore Incidence, DACO: 4.8
1551948	1985, DPX-T6376 herbicide., DACO: 4.8
1551950	1986, DPX-T6376, DACO: 4.8
1551949	1986, Review of Acute Toxicity Studies with Technical DPX-T6376, DACO: 4.8
1551951	1987, DPX-T6376, herbicide, DACO: 4.8
1551953	1987, Metsulfuron Methyl (ALLY) Data submitted in response to telephone request by HPB, February 10, 1987, DACO: 4.8
1551956	1993, Incidence data for lymphosarcoma and histiocytic sarcoma in males in rat study with rimsulfuron, DACO: 4.8
1551957	2002, Methsulfuron Methyl Technical Herbicide; Reg. No. 20213 - Sub No. 2001-1938, DACO: 4.8
1551954	DPX-T6376 (Sub. No. 84-0199), DACO: 4.8

Studies considered in the Environmental Risk Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA Document Number	Reference
1240088	HYDROLYSIS OF 14C-PHENYL-DPX-T6376, DACO: 8.2.1
1205217	PHOTODEGRADATION OF [TRIAZINE-2-14C] METSULFURON METHYL IN WATER, DACO: 8.2.1
1205216	PHOTODEGRADATION OF [TRIAZINE-2-14C] METSULFURON METHYL ON SOIL, DACO: 8.2.1
1240091	14C-DPX-T6376 AEROBIC SOIL DISSIPATION STUDY IN THE GREENHOUSE, DACO: 8.2.3.1
1205219	AEROBIC DEGRADATION OF 14C-CHLOROSULFURON AND 14C-METSULFURON METHYL IN PH 9 UTAH SOIL, DACO: .2.3.1
1240089	AEROBIC SOIL METABOLISM OF 14C-PHENYL-LABELLED-DPX-T6376, DACO: 8.2.3.1

PMRA Document Number	Reference
1204435	AEROBIC SOIL METABOLISM OF [PHENYL(U)-14C] DPX-T6376 IN 7 CANADIAN SOILS (AMR-1001-87), DACO: 8.2.3.1
1248008	ANAEROBIC AQUATIC METABOLISM OF METSULFURON METHYL, DACO: 8.2.3.1
1076025	1986, New hydrolysis products of [triazine-2-14C] metsulfuron methyl at pH 5., DuPont-11411, DACO: 8.2.3.2
1076012	1997, Aerobic soil metabolism of 14C-DPX-T6376., AMR 3768-96, DACO: 8.2.3.4.2
1121011	2000, IN-B5067: Soil degradation at 20C, DuPont-1811; 550/68-D2142, DACO: 8.2.3.4.2
1076013	2001, Anaerobic soil metabolism of [14C]DPX-T6376. Ricerca L.L.C.. DuPont-4618, Amended Report 1., 012820-1-1, DACO: 8.2.3.4.4
1204433	BATCH EQUILIBRIUM ADSORPTION STUDY WITH DPX-T6376 IN 8 CANADIAN SOILS (AMR-871-87), DACO: 8.2.4.1
1121010	1999, IN-B5067: Adsorption/desorption in soil, DuPont-1810; 550/59, DACO: 8.2.4.2
1121008	1999, [14C]IN-A4098: Adsorption/desorption in soil, DuPont-1805; 550/56, DACO: 8.2.4.2
1121006	2000, Rates of degradation of [14C]INA4098, a metabolite of metsulfuron methyl, chlorsulfuron, and thifensulfuron methyl, in three aerobic soils, DACO: 8.3.2
1205299	FIELD SOIL DISSIPATION OF 14C-METSULFURON METHYL ON UNITED STATES AND CANADIAN SOILS, DACO: 8.3.2.3
1204312	DETERMINATION OF THE TOXICITY TO THE EARTHWORM, DACO: 9.2.3.1
1205311	ACUTE CONTACT LD 50 STUDY IN HONEY BEES, DACO: 9.2.4.1
1076017	1998, Metsulfuron Methyl Technical (DPX-T6376): Acute 061 and contact toxicity to the honey bee, Apis mellifera L., AMR 5182-98, DACO: 9.2.4.1,9.2.4.2
1120998	1997, Metsulfuron methyl 60WG (DF): laboratory acute toxicity to the green lacewing, Chrysoperla carnea steph. (Neuroptera: Chrysopidae), 97-022-1033;1033.012.281, DACO: 9.2.8
1121002	1999, Metsulfuron Methyl (DPX-T6376) 20 WG: A laboratory study to evaluate the effects on the ground beetle, Poecilus cupreus L.

PMRA Document Number	Reference
	(Coleoptera: Carabidae), DACO: 9.2.8
1121000	1999, Metsulfuron methyl (DPX-T6376) 20 WG: A laboratory study to evaluate the effects on the parasitic wasp Aphidius rhopalosiphi (Hymenoptera, braconidae), DACO: 9.2.8
1121001	1999, Metsulfuron methyl (DPX-T6376) 20 WG: A laboratory study to evaluate the effects on the predatory mite, Typhlodromus pyri (Acari: Phytoseiidae), DACO: 9.2.8
1121021	1999, IN-A4098: static, acute, 48-hour EC50 to Daphnia magna, DuPont-3247; 12851; 241, DACO: 9.3.2
1076028	2001, Metsulfuron methyl (DPX-T6376) technical: static, acute, 48-hour toxicity test to Daphnia magna., DuPont-6023, DACO: 9.3.2
1076026	Static acute 48-hour EC50 of DPX- T6376-74 to fed Daphnia magna. HLR 748-88 RE. UNPUB. Non-GLP, DACO: 9.3.2
1076030	1989, Chronic toxicity of DPX-T6376-74 to daphnia magna., HLR 833-88 RE, DACO: 9.3.3
1076031	1998, DPX-T6376: A semi-static life- cycle toxicity test with the cladoceran (Daphnia magna)., AMR 5025-98, DACO: 9.3.3
1121023	1999, IN-A4098: 21-day chronic toxicity to Daphnia magna, DuPont-3344; 12238; 254, DACO: 9.3.3
1076032	1986, Acute toxicity of H-16,442 to the crayfish (Procambarus clarki)., HLO 58-87 RE, DACO: 9.4.2
1076034	1988, Static acute 96-hour LC50 LF DPX T6376-75 to rainbow trout (Salmo gairdneri)., HLR 816-88 RE, DACO: 9.5.2.1
1076035	1998, DPX-T6376: A 96-hour static acute toxicity test with the rainbow trout (Oncorhynchus mykiss). Wildlife International Ltd (USA), AMR 5023-98. UNPUB. GLP, AMR 5023-98, DACO: 9.5.2.1
1240098	48-HOUR LC50 TO DAPHNIA MAGNA, DACO: 9.5.2.1
1240097	96-HOUR LC50 TO BLUEGILL SUNFISH, DACO: 9.5.2.1
1240099	96-HOUR LC50 TO RAINBOW TROUT, DACO: 9.5.2.1
1076036	1988, Static acute 96-hour LC50 LF DPX T6376-75 to Bluegill Sunfish (lepomis macrochirus)., HLR 832-88 RE, DACO: 9.5.2.2
1076037	1998, DPX-T6376: A 96-hour static acute toxicity test with the Bluegill Sunfish (lepomis macrochirus)., AMR 5024-98, DACO: 9.5.2.2
1076038	1996, Early Life Stage toxicity of DPX-T6376 (metsulfuron methyl) to rainbow trout (Oncorhynchus mykiss)., HLR 182-96REVO1,VO 2 and VO 3, DACO: 9.5.3.1

PMRA Document Number	Reference
1240093	ACUTE ORAL LD50 - MALLARD DUCK - INT-6376-18, DACO: 9.6.2.1
1240095	8-DAY DIETARY LC50 - BOBWHITE QUAIL, DACO: 9.6.2.4
1240094	8-DAY DIETARY LC50 - MALLARD DUCK, DACO: 9.6.2.4
1076039	1996, DPX-T6376 (metsulfuron methyl) a Reproduction Study in the Northern Bobwhite (Colinus virginianus)., AMR 3412-95 RE, DACO: 9.6.3.1
1076040	1996, DPX-T6376 (metsulfuron methyl) a Reproduction Study with the Mallard (Anas platyrhynchos))., AMR 3413-95 RE, DACO: 9.6.3.2
1076041	1989, The Algistatic Activity of DPX-T6376 technical to blue green algae., DPC 15/90109 RE, DACO: 9.8.2
1076042	1997, DPX-T6376: Influence on growth and reproduction of anabaena flosaquae., 43308, DACO: 9.8.2
1076043	1997, DPX-T6376: influence on growth and reproduction of navicula pelliculosa ., AMR 3841-96 and 43307, DACO: 9.8.2
1240097	96-HOUR LC50 TO BLUEGILL SUNFISH, DACO: 9.5.2.1
1240099	96-HOUR LC50 TO RAINBOW TROUT, DACO: 9.5.2.1
1076036	1988, Static acute 96-hour LC50 LF DPX T6376-75 to Bluegill Sunfish (lepomis macrochirus)., HLR 832-88 RE, DACO: 9.5.2.2
1076037	1998, DPX-T6376: A 96-hour static acute toxicity test with the Bluegill Sunfish (lepomis macrochirus)., AMR 5024-98, DACO: 9.5.2.2
1076038	1996, Early Life Stage toxicity of DPX-T6376 (metsulfuron methyl) to rainbow trout (Oncorhynchus mykiss)., HLR 182-96REVO1,VO 2 and VO 3, DACO: 9.5.3.1
1240093	ACUTE ORAL LD50 - MALLARD DUCK - INT-6376-18, DACO: 9.6.2.1
1240095	8-DAY DIETARY LC50 - BOBWHITE QUAIL, DACO: 9.6.2.4
1240094	8-DAY DIETARY LC50 - MALLARD DUCK, DACO: 9.6.2.4
1076039	1996, DPX-T6376 (metsulfuron methyl) a Reproduction Study in the Northern Bobwhite (Colinus virginianus)., AMR 3412-95 RE, DACO: 9.6.3.1
1076040	1996, DPX-T6376 (metsulfuron methyl) a Reproduction Study with the Mallard (Anas platyrhynchos))., AMR 3413-95 RE, DACO: 9.6.3.2
1076041	1989, The Algistatic Activity of DPX-T6376 technical to blue green algae., DPC 15/90109 RE, DACO: 9.8.2
1076042	1997, DPX-T6376: Influence on growth and reproduction of anabaena flosaquae., 43308, DACO: 9.8.2

PMRA Document Number	Reference
1076043	1997, DPX-T6376: influence on growth and reproduction of navicula pelliculosa ., AMR 3841-96 and 43307, DACO: 9.8.2
1121005	2004, IN-D5803: Influence on growth rate of the duckweed, Lemna gibba, 2729-DU; 15118, DACO: 9.8.5
1076049	Effects of Ally herbicide (metsulfuron methyl) on four species of freshwater aquatic plantsUSD/ARS., 6376/ME 8 RE, DACO: 9.8.5
1076014	1999. Degradability and fate of metsulfuron methyl in the aquatic environment (water/sediment system). Institut Fresenius, Chemische und Biologische Laboratorien GmbH. Germany. Laboratory report number IF-98/30518-00. Sponsor: E.I. du Pont de Nemours and Co. Wilmington, DE. Sponsor Study No. DuPont-1780. DACO 8.2.3.5.4.
1121025	1999. IN-A4098: Static, Acute, 96-hour, limit test to rainbow trout Oncorhynchus mykiss. Laboratory and Sponsor: E.I. Du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine, Newark, Delaware. Report Number DuPont-3559. DACO 9.5.2.1.
1121026	2000. [14C]IN-A4098: Adsorption/desorption in soil. Performing Laboratory: Covance Laboratories Europe (CLE) North Yorkshire, England, Covance Study No. 550/80. Sponsor: E.I. du Pont de Nemours and Company, Wilmington, Delaware, USA, Report Dumber DuPont-3832. DACO 8.2.4.3.

B. ADDITIONAL INFORMATION CONSIDERED

Published Information

1991, Issue No: 38 Food and Environment Protection Act, 1985, Part III Control of Pesticides Regulations 1986 Evaluation of Fully Approved or Provisionally Approved Products Evaluation on: Metsulfuron Methyl, Dept for Env. Food & Rural Affairs, Pesticid
Allan J. Cessna et al, 2006, Persistence of the Sulfonylurea Herbicides Thifensulfuron-methyl, Ethametsulfuron-methyl and Metsulfuron Methyl in Farm Dugouts (ponds), DACO: 8.6
Battaglin, W.A., E.T. Furlong, M.R. Burkhardt, C. J. Peter., 2000, Occurrence of Sulfonylurea, Sulfonamide, Imidazolinone, and other Herbicides in Midwestern Rivers, Reservoirs, and Groundwater, 1998. Sci. Total Environ. 248:123-133, DACO: 8.6
Daiker D.H., 2005, Lake Wales Ridge Monitoring Network Update. Bureau of Pesticides. Scientific Evaluation Section. http://www.flaes.org/pdf/PRC_MN_2005_01Att.pdf , DACO: 8.6
Julie Klotzbach et al, 2004, Metsulfuron Methyl - Human Health and Ecological Risk Assessment.Peer Review Draft, DACO: 8.6
Michael, J.L., D.G. Neary, J. Fischer and H. Gibbs., 1991, Metsulfuron in surface groundwater of a North Florida flatwoods. Proc. South. Weed Sci. Soc. 44:233-237., DACO: 8.6
Smith, A.E., Persistence of the Herbicides [14C] Chlorsulfuron and [14C] Metsulfuron Methyl in Prarie

Soils under Laboratory Conditions. IN: Bull. Environ. Contam. Toxicol. (1986) 37:698-704, DACO: 8.6
Fairchild, J. et al, 1997, Comparative Sensitivity of Selenastrum capricornutum and Lemna minor to Sixteen Herbicides. Arch. Environ. Contam. Toxicol. 32, 353-357 (1997), Archives of Environmental Contaimination and Toxicology Vol 32 pp 353-357. 1997., DA
Christian Kjaer et al, Effects on hawthorn the year after simulated spray drift in Chemosphere 63 (2006) 853-859, DACO: 9.9
Christian Kjaer et al, Metsulfuron spray drift reduces fruit yield of hawthorn (Crataegus monogyna L.) in Science of the Total Environment 356 (2006) 228-234, DACO: 9.9
Nina Cedergreen et al, Sensitivity of aquatic plants to the herbicide metsulfuron methyl in Ecotoxicology and Environmental Safety 57 (2004) 153-161, DACO: 9.9

Unpublished Information

PMRA Document Number	Reference
1566615	2004, Pesticide Science Fund Results for 2003-2004: Sulfonyl-ureas in Canadian prairie reservoirs, rivers, dugouts and wetlands. , DACO: 8.6
1566613	2005, Pesticide Science Fund Results for 2003-2005: Sulfonyl-ureas measured in Canadian prairie reservoirs., DACO: 8.6

Studies considered in the Value Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA Document Number	Reference
1406316	2005, Site Specific Use Information, DACO: 10.7.1
1406317	2005, Product Specific Use Information, DACO: 10.7.2